

ISSUES UNIQUE TO CALIFORNIA CLINICAL LABORATORY LAW
California Department of Health Services
Laboratory Field Services
April 2004

Disclaimer:

Please note that no accreditation organizations have been approved by the California Department of Health Services to evaluate laboratory compliance with state law. As such, it is the responsibility of the director of an accredited laboratory to ensure that his or her laboratory complies with state law. We recommend that each laboratory director be aware of all applicable statutes and regulations which may affect his or her laboratory practice. California's clinical laboratory laws are found at Business and Professions Code (BPC) section 1200 et. seq., and its regulations are found at Title 17 California Code of Regulations (CCR), section 1029 et. seq." These can be found at www.leginfo.ca.gov/calaw and www.calregs.com respectively.

Requirements for licensed clinical laboratories, as of April 2004, include, but are not limited to, the following:

I. LABORATORY DIRECTOR REQUIREMENTS AND RESPONSIBILITIES

- A. All laboratories require a laboratory director who is a CA-licensed physician/surgeon, master or doctoral scientist, or master of doctoral bioanalyst. This includes registered laboratories performing waived tests. (BPC 1209)(a))
- B. Laboratory director of a general acute care hospital must be a board-certified pathologist. A licensed physician/surgeon or bioanalyst may serve in absence of pathologist, but pathologist must be available. (BPC 1209 (f)) Other non-pathologist physician section directors can serve as Technical Supervisors, but not directors in general acute care hospitals. (CCR 1036.4)
- C. A licensed doctoral scientist, as a clinical chemist, clinical microbiologist, clinical toxicologist, may serve as laboratory director limited to their specialty. (BPC 1264)
- D. A licensed bioanalyst may serve as laboratory director of an acute care hospital if a qualified pathologist is not available, but a pathologist must be available for consultation. (BPC 1209 (f))
- E. A director of a histocompatibility laboratory must be licensed physician/surgeon, a bioanalyst, or a doctoral scientist who has 4 years experience in histocompatibility and is licensed in California. (BPC 1209.1)



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- F. An interim laboratory director can be appointed within 5 days of a major change of director if a laboratory is left without a director. (BPC 1265 (e)(2))
- G. The Department must be notified within 30 days of a major change in laboratory director. (BPC 1265 (g))
- H. Cytogenetic laboratory director must be a licensed clinical cytogeneticist, pathologist or bioanalyst who meets CLIA requirements for cytogenetic laboratory director. (CCR 1030.7)
- I. An oral pathology laboratory director must be a board certified pathologist or a dentist licensed by DHS as oral pathology laboratory director. (CCR 1030.8)
- J. A pathologist shall be available daily in any laboratory and serve as director of no more than three (3) laboratories. The director must sign all abnormal reports and all non-gynecological reports, and must be available daily. (CCR 1050 (c))
- K. A laboratory director is excluded from directing another laboratory for 2 years when the Laboratory license is revoked. (CCR 1065.3)

II. LABORATORY SUPERVISORS

- A. Clinical Consultants must be licensed to direct a clinical laboratory in California or to practice medicine. (CCR 1036)
- B. General Supervisors must be licensed to perform high complexity tests or CA-licensed physician/surgeon plus must have 2 years experience. The General Supervisor must provide day-to-day supervision and must be accessible. (CCR 1036.1)
- C. Moderate complexity Technical Consultant must be licensed to perform high complexity testing in CA or to practice medicine plus must have 2 years experience. (CCR 1036.2)
- D. Waived laboratory Technical Consultant must be qualified as a testing person authorized under BPC 1206.5 (a), must have a baccalaureate degree, must be a licensed healthcare professional, must have one-year experience and must be competent in tests he/she is supervising. (CCR 1036.3)
- E. Technical Supervisors must be licensed to perform high complexity testing or practice medicine in CA. MD/PhD must have 1 year experience, MS, 2 years and BS, 4 years experience. (CCR 1036.4)

III. TESTING PERSONNEL

- A. Testing personnel approved to perform each complexity test are listed at BPC 1206.5. IMPORTANT!
- B. Persons performing high complexity testing generally require a baccalaureate-level license. (BPC 1261)

- C. Persons with a baccalaureate-level license may serve as technical consultant, technical supervisor, and general supervisor when they have adequate experience or training. (BPC 1210)
- D. Persons with a baccalaureate-level license in a specialty may perform waived or moderate complexity testing in any other specialty. (BPC 1210)
- E. Baccalaureate-level licenses generally require a BS in science, one year training, an examination, payment of license fees, and 12 hours of continuing education each year to maintain a license. (BPC 1210, 1275, CCR 1031)
- F. A licensed baccalaureate-level clinical chemist scientist may perform high complexity tests in chemistry, including routine chemistry, clinical microscopy, endocrinology, toxicology; immunology, including diagnostic immunology and serology; and molecular biology. (CCR 1031(b)(1))
- G. A licensed baccalaureate-level clinical microbiologist scientist may perform high complexity tests in microbiology including bacteriology, mycobacteriology, mycology, parasitology, and virology, immunology, including diagnostic immunology and syphilis serology, and molecular biology. (CCR 1031(b)(2))
- H. A licensed baccalaureate-level clinical immunohematologist scientist may perform high complexity tests in immunohematology including ABO/Rh blood grouping and typing, unexpected antibody detection, compatibility testing and antibody identification. (CCR 1031(b)(3))
- I. A licensed baccalaureate-level clinical toxicologist scientist may perform high complexity tests in to the specialty of toxicology. (CCR 1031(b)(4))
- J. A licensed baccalaureate-level clinical hematologist scientist may perform high complexity tests in hematology including routine hematology and coagulation. (CCR 1031(b)(5))
- K. A physician office laboratory (five or fewer physicians performing tests only on their own patients) may employ any person to perform testing, but physician must be present when high complexity tests are done. (BPC 1206.5(b) (c))
- L. A temporary license may be issued to a baccalaureate-level scientist applicant who is otherwise eligible to take a state-administered licensing examination. This temporary license is valid until the results of the next examination are available at which time the temporary license will either be revoked or the person issued a permanent license. (BPC 1262)

IV. LABORATORY AIDES

- A. Unlicensed laboratory personnel ("aides") cannot perform tests. (BPC 1212)
- B. Unlicensed persons require direct and constant supervision during entire time they are assisting in analytical phase. (BPC 1206(a)(8))

- C. Unlicensed persons performing pre-analytical and post-analytical procedures require supervision and control of licensed person. (BPC 1269)
- D. There are limitations on what activities an unlicensed person can do in a laboratory. (BPC 1269) IMPORTANT!

V. LABORATORY OWNERS

- A. Anyone with a 5% or more interest in a laboratory is considered an owner. (BPC 1211)
- B. A major change of owner is one which involves 50% or more of ownership control. (BPC 1211)
- C. If the laboratory director(s) is not the laboratory owner(s), then both are jointly and severally responsible for the laboratory. (BPC 1265 (b))
- D. The laboratory owner must state name(s) and address(es) on the application. (BPC 1265(b))
- E. The Department must be notified within 30 changes of a major change of owner. (BPC 1265 (g))
- F. The laboratory owner is excluded from owning another laboratory when his laboratory license is revoked. (CCR 1065.3)

VI. PHLEBOTOMY

- A. Phlebotomy can be performed by persons licensed under BPC chapter 3. (BPC 1242)
- B. Phlebotomy can be performed by RN, LVN, and RCP. (BPC 1242.6)
- C. Phlebotomy can be performed by a licensed trainee. (BPC 1243)
- D. Phlebotomy can be performed by a certified phlebotomist who must be employed by a laboratory. (BPC 1246). Exceptions to this, starting 2004, are listed in F, below.
- E. Phlebotomy certification requirements changed in April 2003 and all phlebotomist currently performing phlebotomy have 3 years to get the new certification. Certification requirements and scopes of practice are stated in California law. (CCR 1034)
- F. A Certified Phlebotomy Technician may work outside a clinical laboratory to perform phlebotomy for non-diagnostic (insurance) purposes or for forensic purposes when they follow policy and procedures established by a physician and are supervised by a nurse or clinical laboratory scientist, (BPC 1246 (c))

VII. TRAINEES

- A. All trainees must train in a program approved by the Department. BPC 1222.5)
- B. Trainees must work under direct and responsible supervision of the director or person other than a trainee licensed under BPC chapter 3. (BPC 1205)
- C. The ratio of licensed person to trainee must not exceed 2:1. (CCR 1038.1)

VIII. APPLICATION OF CLINICAL LABORATORY LAW

- A. California law is broadly applied to include all facilities providing analyses of all body specimens including blood, urine, feces, hair, breath, saliva, and body fluids. (BPC 1206)
- B. Laboratories outside CA performing tests on specimens originating from CA must be licensed. (BPC 1208 (a))
- C. Exempt from laboratory law are those owned by US government, public health laboratories, forensic laboratories, research/teaching laboratories, SAMSHA laboratories, childcare centers performing glucose on diabetic children, persons doing over-the-counter purchased home test kits, EMT/paramedics en route to hospital performing glucose. (BPC 1241(b))
- D. All laboratories performing moderate/high complexity HIV antibody tests must be licensed. (HSC 208 and 1603.1)
- E. All laboratories performing cytology must be licensed. (BPC 1271(d))
- F. Laboratory licenses and personnel licenses must be posted in plain view. (BPC 1266)
- G. Separate licenses not needed for mobile laboratories, not-for-profit or government laboratories performing <15 waived or moderate tests, laboratories within a hospital operating under single license, laboratories at the same address under common ownership. (BPC 1265 (d))
- H. Laboratories must notify the Department of Consumer Affairs when they notice an unlocked specimen storage box. (BPC 1220.5)
- I. Laboratory must notify the Department within 30 days of any change of name or address. (BPC 1227)
- J. Laboratories must report infectious diseases to appropriate county health officer. (CCR 2505)
- K. Laboratories must keep all records for 3 years, cytology for 5 years, cytology reports and histopathology reports for 10 years. (CCR 1050)

- L. All clinical laboratory results must be reviewed and released by licensed persons, to the healthcare provider who ordered the tests. (CCR 1050 (h) and BPC 1288)
- M. Laboratories may accept self-ordered tests only for those that are approved by the FDA for over-the-counter purchase for home testing. (BPC 1246.5))
- N. All laboratory reports must show the name of the laboratory director of the laboratory performing the test. (CCR 1050)
- O. Blood banks (HSC 1635-) and tissue banks (HSC 1600 -) need to be licensed separately from clinical laboratories.

IX. PROFICIENCY TESTING

- A. Laboratories must authorize PT provider to release results to Department in an electronic format compatible with state's monitoring system. (BPC 1220(a)(1)(B) and CCR 1066(d)(2))
- B. Laboratories must enroll in state-approved PT provider. (BPC 1272)
- C. Laboratories approved for moderate/high complexity HIV antibody tests must enroll in PT. (CCR 1230)
- D. Laboratories must follow all CLIA PT requirements. (BPC 1220)
- E. A laboratory license is subject to revocation for referring PT to another laboratory. (CCR 1065.45)

X. CYTOLOGY LABORATORIES

- A. Cytotechnologists cannot perform more than 80 Pap smears in a 24-hour period. If the cytotechnologist has other duties, the 80-slide limit shall be reduced appropriately. (BPC 1271)
- B. Cytotechnologists must record the number of cases performed each day at each location they work. (BPC 1271)
- C. The location that cytology is performed must be identified on the report. (BPC 1271)
- D. Ten percent of all normal and all abnormal cytology cases must be reviewed by pathologist or supervising cytotechnologist. (BPC 1271)
- E. Cytology laboratories must send quarterly reports of all dysplasia to doctors and review previous normal cases. (BPC 1274)
- F. The laboratory director must sign all abnormal cytology cases and all non-gynecological reports. (CCR 1050 (f)(3))
- G. Anyone who reviews a cytology case must sign the worksheet or report, even if they disagree with the final report. (CCR 1050 (f)(3))

XI. CALIFORNIA LAW SAYS IT IS UNLAWFUL TO:

- A. Pose as a licensed person when not. (BPC 1280)
- B. Operate a laboratory without a license. (BPC 1281)
- C. Buy or sell blood. (BPC 1281.1)
- D. Operate a laboratory unless licensed as a physician. (BPC 1282)
- E. Perform phlebotomy unless authorized. (BPC 1282.2)
- F. Adversely impact the integrity of a specimen. (BPC 1282.3)
- G. Serve as a “nominal” director. (BPC 1284)
- H. Perform tests unless licensed or authorized. (BPC 1285)
- I. Conduct a school without approval. (BPC 1286)
- J. Accept a test without a physician referral. (BPC 1288)
 - Perform tests outside specialty approval. (BPC 1288.5)